TAB J



UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION

MDL NO. 1456 Civil Action No. 01-12257-PBS

THIS DOCUMENT RELATES TO ALL CLASS ACTIONS

Hon. Patti B. Saris

PLAINTIFFS' SUPPLEMENTAL RESPONSE TO THE J&J DEFENDANTS' REQUESTS FOR ADMISSION AND INTERROGATORIES CONCERNING REMICADE®

Plaintiffs submit this Supplemental Response to the Johnson & Johnson Defendants' Requests for Admissions and Interrogatories as follows.

OBJECTIONS

- This Supplemental Response is made while Plaintiffs' Objections to the November 9, 2005 ruling of Magistrate Judge Bowler are pending. Plaintiffs reserve the right to withdraw this Supplemental Response based on the disposition of the Objections.
- The Responses contained herein are based on the data available to Plaintiffs as of this date. Plaintiffs reserve the right to amend or modify these Responses if additional data becomes available.
- Plaintiffs object to the J&J Defendants' "definitions" to the extent they create obligations broader than what is required by the Federal Rules of Civil Procedure.
- 4. Plaintiffs object to the J&J Defendants' Requests and Interrogatories to the extent they seek information which is the subject of expert analysis and opinion.

DEFENDANT'S EXHIBIT 2782 Plaintiffs object to the J&J Defendants' Interrogatories to the extent they seek the factual basis for any denial, when such denial is based on the absence of facts or information.

REQUEST TO ADMIT NO. 1:

Admit that Centocor began selling Remicade® in 1998.

RESPONSE TO REQUEST TO ADMIT NO. 1:

Admitted.

INTERROGATORY NO. 1: If your response to Request to Admit No. 1 contains a denial, in whole or in part, describe the basis for your denial, and identify all documents and testimony that you rely on to support your denial.

RESPONSE TO INTERROGATORY 1:

Not Applicable.

REQUEST TO ADMIT NO. 2: Admit that from 1998 to the present, the published AWP for Remicade® has been 130% of the published WAC for Remicade®.

RESPONSE TO REQUEST TO ADMIT NO. 2:

Admitted.

INTERROGATORY NO. 2: If your response to Request to Admit No. 2 contains a denial, in whole or in part, describe the basis for your denial, and identify all documents and testimony that you rely on to support your denial.

RESPONSE TO INTERROGATORY NO. 2:

Not applicable.

REQUEST TO ADMIT NO. 3: Admit that from 1998 to the present, Centocor, Inc. has not paid rebates on Remicade® to physicians who purchase or dispense Remicade®.

RESPONSE TO REQUEST TO ADMIT NO. 3:

Admitted. This Response is based on the definition of rebates articulated at the November 9, 2005 hearing, see transcript pages 10-11, and based on the rebate data produced by Centocor to date.

INTERROGATORY NO. 3: If your response to Request to Admit No. 3 contains a denial, in whole or in part, describe the basis for your denial, and identify all documents and testimony that you rely on to support your denial.

RESPONSE TO INTERROGATORY NO. 3:

Not applicable.

REQUEST TO ADMIT NO. 4: Admit that from 1998 to the present, Centocor, Inc. has not paid rebates on Remicade® to pharmacy benefit managers.

RESPONSE TO REQUEST TO ADMIT NO. 4:

Admitted. This admission is based on the definition of rebates articulated at the November 9, 2005 hearing, see transcript pages 10-11. This admission is also based on the rebate data produced by Centocor to date.

INTERROGATORY NO. 4: If your response to Request to Admit No. 4 contains a denial, in whole or in part, describe the basis for your denial, and identify all documents and testimony that you rely on to support your denial.

RESPONSE TO INTERROGATORY NO. 4:

Not applicable.

REQUEST TO ADMIT NO. 5: Admit that from 1998 to the present, the only rebates that Centocor, Inc. has paid on Remicade® have been rebates paid to persons or entities that reimburse for Remicade®, such as Health Maintenance Organizations and Preferred Provider Organizations.

RESPONSE TO REQUEST TO ADMIT NO. 5:

Denied. This Response is based on the definition of rebates articulated at November 9, 2005 hearing, see transcript pages 10-11. This response is based on the rebate data produced by Contocor to date.

INTERROGATORY NO. 5: If your response to Request to Admit No. 5 contains a denial, in whole or in part, describe the basis for your denial, and identify all documents and testimony that you rely on to support your denial.

RESPONSE TO INTERROGATORY NO. 5:

The electronic rebate data produced by Centocor does not show payments to HMOs, but does show rebate payments to hospitals and others that are apparently not Preferred Provider Organizations. Some of these payments appear to be called "VOO" by Centocor. Centocor's electronic data was discussed at the deposition of Centocor's Michelle Murphy. This Response is based on the definition of rebates articulated at the hearing of November 9, 2005.

REQUEST TO ADMIT NO. 6: Admit that from 1998 to the present, the rebates that Centocor, Inc. has paid on Remicade® have reduced the net reimbursement cost of Remicade® for those payors that have received rebates.

RESPONSE TO REQUEST TO ADMIT NO. 6:

Admitted in part, denied in part. Admitted that, in theory, those payors who actually received rebates from Centocor incurred a reduction in the Net Reimbursement Cost of Remicade, as that term is defined by Centocor. It is denied that payors actually received any rebates on Remicade. This response is based on the limitations of the Request for Admissions as stated by the parties at the November 9, 2005 hearing.

INTERROGATORY NO. 6: If your response to Request to Admit No. 6 contains a denial, in whole or in part, describe the basis for your denial, and identify all documents and testimony that you rely on to support your denial.

RESPONSE TO INTERROGATORY NO. 6:

The electronic rebate data produced by Centocor does not indicate what rebates, if any, were ultimately paid to payors. This response is based on the limitations of the Request for Admissions as stated by the parties at the November 9, 2005 hearing.

REQUEST TO ADMIT NO. 7: Admit that from 1998 to the present, the rebates that Centocor, Inc. has paid on Remicade® have reduced the spread.

RESPONSE TO REQUEST TO ADMIT NO. 7:

Objection. The term "spread" as defined by Centocor is vague and ambiguous, and differs substantially from the definition of spread used by Plaintiffs in this litigation. Further, the Request is objectionable as a burdensome contention interrogatory that would require plaintiffs to research sources of documents in the possession of J&J, when J&J could just as easily collected this information and presented the basis for the RFA. This Request also seeks an admission which is not relevant.

INTERROGATORY NO. 7: If your response to Request to Admit No. 7 contains a denial, in whole or in part, describe the basis for your denial, and identify all documents and testimony that you rely on to support your denial.

RESPONSE TO INTERROGATORY NO. 7:

Objection. The term "spread" as defined by Centocor is vague and ambiguous, and differs substantially from the definition of spread used by Plaintiffs in this litigation. Further, this Interrogatory also seeks information which is not relevant.

REQUEST TO ADMIT NO. 8: Admit that from 1998 to the present, the spread on Remicade® has not exceeded the difference between its published WAC and its published AWP for all persons or entities that reimbursed Remicade at or below its AWP.

RESPONSE TO REQUEST TO ADMIT NO. 8:

Denied.

INTERROGATORY NO. 8: If your response to Request to Admit No. 8 contains a denial, in whole or in part, describe the basis for your denial, and identify all documents and testimony that you rely on to support your denial.

RESPONSE TO INTERROGATORY NO. 8:

Objection. The term "spread" as defined by Centocor is vague and ambiguous, and differs substantially from the definition of spread used by Plaintiffs in this litigation. Further, this Interrogatory also seeks information which is not relevant. The Court ruled on November 9, 2005 that Plaintiffs did not have to provide their calculation of the "net acquisition cost" for Remicade, which is a component of the "spread" as defined by Centocor. Plaintiffs have provided herein the WAC and AWP prices for Remicade as well as an aggregate calculation of "net reimbursement cost", which is another component of "spread".

INTERROGATORY NO. 9: From 1998 to the present, state each published WAC and each published AWP for Remicade®, and the effective date of each change in Remicade®'s WAC and AWP.

RESPONSE TO INTERROGATORY NO. 9:

A listing of the WAC and AWP pricing for Remicade, based on the information currently available to Plaintiffs, is attached as Exhibit A.

INTERROGATORY NO. 10: State the ASP for Remicade® for each of the time intervals between the changes in Remicade®'s WAC and AWP identified in response to Interrogatory No. 9.

RESPONSE TO INTERROGATORY NO. 10:

A listing of the ASP for Remicade, calculated annually, is attached as Exhibit B. These calculations are based on the best available data provided to Plaintiffs by defendant and subject to all caveats and qualifications relating to such calculations as set forth more fully in Plaintiffs' forthcoming expert report. Plaintiffs reserve the right to supplement these calculations in light of any additional information that is provided to Plaintiffs.

INTERROGATORY NO. 11: State the average net reimbursement cost and the average net acquisition cost for Remicade® for each of the time intervals between the changes in Remicade®'s WAC and AWP identified in response to Interrogatory No. 9.

RESPONSE TO INTERROGATORY NO. 11:

Objection. This Interrogatory seeks information which is not relevant, nor calculated to lead to the discovery of admissible evidence. The Court ruled on November 9, 2005 that Plaintiffs did not have to provide their calculation of the "net acquisition cost" for Remicade.

Without waiving such objections, Plaintiffs state that the average net reimbursement cost for all drugs in this litigation, including Remicade, for private, non-governmental payors, is 97.5% of AWP. The net reimbursement cost for governmental payors is determined by statute.

Dated: December 13, 2005.

-By /s/ John A. Macoretta
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Samuel D. Heins Alan I. Gilbert Susan B. MacMenamin Heins, Mills & Olson, P.C. 3550 IDS Center 80 South Eighth Street Minneapolis, MN 55402 Telephone: (612) 338-4605 Facsimile: (612) 338-4692 CO-LEAD COUNSEL FOR PLAINTIFFS

CERTIFICATE OF SERVICE

I hereby certify that on December 13, 2005 I caused a true and correct copy of the Plaintiffs' Supplemental Response to J&J Defendants' Requests for Admission and Interrogatories Concerning Remicade® to be served on all counsel of record by electronic service via Lexis/Nexis, pursuant to Case Management Order No. 2.

/s/John Macoretta
John Macoretta

EXHIBIT A

REMICADE PRICING HISTORY

Date .	AWP	WAC
At Launch - September 1998	\$585.00	\$450.00
Price Increase - June 18, 1999	\$611.33	\$470.25
Price Increase - April 1, 2000	\$641.28	\$493.29
Price Increase - November 3, 2000	\$665.65	\$512.04
Price Increase - June 6, 2001	\$691.61	\$532,00

EXHIBIT "B"

Remicade Annual ASPs

		\$517.98
200Z Z00Z 140Z 500Z 4541 9641		\$516.65
E R		\$608.25
8		\$486.17
664		\$458.23
2		\$447.28 \$458.23 \$488.17 \$508.25 \$518.65 \$514.98
		1PCK US PD
		57894003001 C16SJ REMICADE 1PCK US PD
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TAB K

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

In Re:

PHARMACEUTICAL INDUSTRY

AVERAGE WHOLESALE PRICE

LITIGATION

) CA No. 01-12257-PBS

MDL No. 1456

) Pages 2-1 - 2-204

BENCH TRIAL - DAY TWO

BEFORE THE HONORABLE PATTI B. SARIS UNITED STATES DISTRICT JUDGE

United States District Court 1 Courthouse Way, Courtroom 19 Boston, Massachusetts November 7, 2006, 9:15 a.m.

LEE A. MARZILLI and TIMOTHY J. WILLETTE
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617)345-6787

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					Page 3
1		I N D E X			
2	WITNESS	DIRECT	CROSS	REDIRECT	RECROSS
3	Sharon Faulkner		2-4		
4	Gina Alongi	2-24	2-34	2-63	2-68
5	Anna Choice	2-71	2-76		
6	Rebecca Hopkins	2-91	2-110		
7	Deborah Devaux	2-126	2-144 2-174	2-178	
8	Minhaal Mulmour	2-184	2 2/1		
9	Michael Mulrey	2-104			
10	EXHIBITS		PAGE		
11	957		2-21		
12	957-A		2-23		
13	3000, 3001, 3002, 1502		2-43		
14	3003		2-83		
15	3004		2-84		
16	4000		2-110		
17	873		2-131		
18	1149		2-177		
19	990		2-177		
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- 1 A. BlueCross wants to pay rates that are not considered to
- be inconsistent with the marketplace, so where we do make a
- change in rate, we like to use a methodology that's generally
- 4 accepted in the industry.
- 5 O. Well, does BlueCross BlueShield consider the cost of
- drugs to physicians an important factor when it chooses to
- 7 reimburse?
- 8 A. The cost of drugs in an individual physician contract?
- 9 Q. Not to a contract, just in general.
- MR. NOTARGIACOMO: Withdraw the question.
- 11 O. Doesn't BlueCross BlueShield consider it important
- whenever it reimburses to use whatever information it has
- about the actual cost to the provider?
- 14 A. Yes. We don't have information about the actual costs
- of these drugs to the physician.
- THE COURT: Well, let me ask you this. Since
- you're a named plaintiff in this, if you had known early on
- when the suit started and before, if you had known that AWP
- was grossly inflated, would you have changed your practices
- 20 at all.
- THE WITNESS: I don't know exactly what we would
- 22 have done. The ideal would be to know what the actual costs
- of the drug to the physician is. We don't have that
- knowledge and we didn't have that knowledge.
- THE COURT: Well, the concern I have is now that

- A. That wasn't the only change that Medicare made.
- Q. I simply asked you -- we're talking about the reasons
- why CMS was considering ASP and what you folks at BlueCross
- BlueShield understood.
- A. I just don't want to give an incomplete answer about
- 6 what we understood. We certainly --
- Q. I'm certainly asking you about the first item here. So
- you were aware about physician spreads and overpayment for
- 9 drugs.
- 10 A. We were aware that the change that Medicare was making
- would reduce the payment for drugs, yes.
- Q. Now -- and you were aware that, according to CMS and
- GAO, there had been a billion-dollar overpayment for Part B
- 14 drugs, correct?
- ¹⁵ A. Yes.
- Q. And again, according to whatever your source was, that
- there had been an allegation of a \$600 million overpayment to
- oncologists in 2002, correct?
- ¹⁹ A. Yes.
- Q. And there was concern about patients being adversely
- 21 affected by an inflated AWP. That's in your document, right?
- ²² A. It is.
- Q. And if we could go to the next page, your group was able
- to compile information as to how CMS intended to calculate
- ²⁵ ASP, correct?

TAB L

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

In Re:

PHARMACEUTICAL INDUSTRY

AVERAGE WHOLESALE PRICE

LITIGATION

) CA No. 01-12257-PBS

MDL No. 1456

) Pages 3-1 - 3-171

BENCH TRIAL - DAY THREE

BEFORE THE HONORABLE PATTI B. SARIS UNITED STATES DISTRICT JUDGE

United States District Court 1 Courthouse Way, Courtroom 19 Boston, Massachusetts November 8, 2006, 9:15 a.m.

LEE A. MARZILLI and TIMOTHY J. WILLETTE
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617) 345-6787

1					Page 3
2					
3		INDE	X		
4	WITNESS	DIRECT	CROSS	REDIRECT	BECDOCC
5		DIRECT			RECROSS
6	Michael Mulrey		3-5 3-44 3-51	3-57	3-67 3-68
8	Maureen Coneys	3-70	3-79	3-104	3-106
9	Kenneth J. Arruda	3-116	3-127		
10					
11					
	EXHIBITS	PAC	E		
12	999	3-2	28		
13	1020 1497	3 - 4 3 - 4			
14	1231	3-1			
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- they're being reasonably compensated?
- THE WITNESS: Yes, in the analysis that we did in
- this PowerPoint presentation. If we're going to move to the
- 4 Medicare reimbursement where they were going to scale down
- 5 the drug pricing and increase the drug administration, there
- 6 was still a negative impact to our provider community.
- THE COURT: Right, because they make fewer profits.
- THE WITNESS: Yes.
- THE COURT: Now, you're a plaintiff in this case,
- 10 right --
- THE WITNESS: Yes.
- THE COURT: -- Blue Cross-Blue Shield? So
- essentially, now that you know everything, the decision was
- made not to change anyway. Is that the bottom line?
- THE WITNESS: The decision was made not to change
- because we didn't know with Medicare moving to the ASP
- pricing what the acceptance would be in the industry. And
- we've all the time when these -- you know, we try to use
- industry standards in setting, you know, a lot of our
- reimbursement methodologies. And, you know, Medicare moving
- to this new pricing methodology, we kind of wanted to take a
- wait-and-see attitude to see what, if any, disruption may be
- caused by providers back towards Medicare.
- THE COURT: All right. So if ten years ago --
- well, maybe not, but let's say after Congress passed the

- statute. If you had known in the late nineties or early
- 2 2000s about these kinds of spreads, would you have done
- 3 anything about it?
- THE WITNESS: If I had known at that point in time
- 5 about the spreads? I would have been hard-pressed-
- THE COURT: In other words, if you had this data in
- the late nineties, early 2000s, because now you know, right?
- THE WITNESS: Yes.
- THE COURT: Now you know. So would you have done
- anything about it?
- THE WITNESS: I -- I probably would have raised it
- to senior management to say, okay, what do we want to do?
- 13 How can we address this situation and what alternatives could
- we have other than relying on AWP pricing?
- THE COURT: Okay.
- 16 BY MR. MANGI:
- Q. Now, Mr. Mulrey, we were just looking at the potential
- impact of a shift from 95 percent of AWP to 85 percent of
- AWP, right?
- ²⁰ A. Yes.
- MR. MANGI: And I'd like to move into evidence,
- your Honor, DX 999, which is the document we just looked at.
- Q. And, Mr. Mulrey, I'd like to draw your attention now to
- another exhibit. That's DX 1497. It'll appear on your
- screen. I'd like to draw your attention to the third page of

TAB M



ORIGINAL

November 5, 1998

C. Kaye Riley, HCPCS Coordinator Health Care Financing Administration CS-08-27 7500 Security Blvd. Baltimore, Maryland 21233-1850

Dear Ms. Riley:

I am pleased to submit the enclosed application for an alpha-numeric code in the Health Cure Financing Administration Common Procedure Coding System (HCPCS) for Remicado^{na} (infliximab), a breakthrough drug for the treatment of Crohn's disease.

Remicaders is indicated for the treatment of moderately to severely active Crohn's disease or the reduction of the signs and symptoms, in patients who have an inadequate response to conventional therapy. It is also indicated as a treatment for patients with fistulizing Crohn's disease for reduction in the number of draining enterocutaneous fistula(s).

Following an expedited review, Remicade™ was approved by the FDA on August 24, 1998 and became available for wholesale purchase on October 5. Rapid and widespread adoption is expected of this new drug by gastroenterologists and other physicians who treat patients with Croha's disease. To date, there have been 85 Medicare orders written for Remicade™. Therefore, I have included in the application a request for the assignment of a temporary code to be assed pending approval of a new code for use beginning January 1, 2000.

A temporary code will facilitate claims processing and reduce the administrative burden with 13490 "Unclassified drugs". Specifically, a temporary code will eliminate the unnecessary and costly submission by physicians and review by carriers of written documentation regarding the drug administrated, the dosage, the route of administration and the charge.

If you have any questions or require any additional information, please do not hesitate to contact me. In particular, if there is anything missing that would preclude consideration of the application at your next HCPCS meeting I would appreciate hearing from you as soon as possible.

I look forward to working with you on the development of the temporary and permanent codes needed to promptly and accumulely report the use of this important advance in the treatment of Crohn's disease.

A A

Centocor, Inc.

Plaintiffs' Exhibit 261 01-12257-PBS

Centocor, Inc. 200 Great Valley Parkway Malvern, Pennsylvania 19355-1307-Telephone (610) 651-6000-Facsimile (610) 651-6100

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HIGHLY CONFIDENTIAL

MDL-CEN00108051

Health Cure Financing Administration
 Common Procedure Coding System (HCPCS)
 Alpha-Numeric Coding Recommendation Format

Submitted by Centocor, inc. November 4, 1998

INFORMATION SUPPORTING CODING MODIFICATION RECOMMENDATION

1. Item trade/trand name: REMICADE®
Generic name: infiltranab

FDA Classification: Chimeric (Human Murine) Monocloral Antibody to Tamor Necrosis Factor (BB-IND 5389/ODA 95-924)

2. Describe the item in general terminology.

Description

Remicade is indicated in the treatment of patients with Crohn's disease, a chronic and debilitating disorder of the gastrointestical tract that can greatly affect a patient's quality of life. The chronic inflammation of Crohn's disease is attributed to an imbalance between pro- and anti-inflammatory mediators, called cytokines regulate inflammation in Crohn's disease. Tumor necrosis factor-or and other pro-inflammatory cytokines predominate in Crohn's disease, resulting in chronic nucesal inflammation. Crohn's disease is neither medically or surgically causable. The goal of treatment is to induce and maintain remission, maintain quality of life, and minimize the toxicity of therapy.

Indication

REMICADE is indicated for treatment of moderately to severely active Crohn's disease or the reduction of the signs and symptoms, in patients who have an imadequate response to conventional therapy. It is also indicated as a treatment for patients with fishalizing Crohm's disease for reduction in the number of draining enterocutaneous fistalia(s).

Artion

REMICADE is the first of a new class of agents that blocks activity of a key biologic response mediator called tumor necrosis factor alpha (TNF-α). It is believed that REMICADE reduces intestinal inflammation in patients with Crohn's disease by binding to and neutralizing TNF-α on the cell membrane and in the blood and by destroying TNF-α producing cells. This action may explain why REMICADE is a particularly effective inhibitor of TNF-α and why REMICADE has a rapid and substantial clinical benefit.

Dosage and Route of Administration

The recommended dose of infliximab is 5 mg/kg given as a single intravenous infusion for treatment of moderately to severely active Croba's disease in patients who have had an inadequate response to conventional therapy. In patients with fistulizing disease, an initial 5 mg/kg dose should be followed with additional 5mg/kg doses at 2 and 6 weeks after the first infusion.

How Supplied

Remicade (inflixings) lyophilized concentrate for injection is supplied individually-boxed singleuse vials in the following strength: NDC 57894-030-01, 100 mg inflixings in a 20-ml vial.

Why are the current code categories impdequate to describe the item?

There are no current code categories that describe this item. Remicade^{ne} is the first anti-TNF inhibitor to receive FDA approval.

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MDL-CEN00108052

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Health Cure Financing Administration
Common Procedure Coding System (HCPCS)

Submitted by Centocor, Inc. November 4, 1998

List any local codes used by any third party payor to process the item.

We are unaware of any local codes in use by third party payers.

If specific codes are not being used, how are you currently billing for the item.

Code J3498 Unclassified drugs is being used. In addition, documentation of the drug administered, the dosage, route of administration and charge is submitted with the claim.

How long has this item been on the market?

Alpha-Numeric Coding Recommendation Format

Remicade™ was commercially available October 5, 1998.

The review timetable is listed below:

- December 30, 1997: Infliximab application submitted
- May 28, 1998: FDA voted manineously to recommend approval of inflicinals
- June 30, 1998: FDA issues a Complete Review letter for inflixingsb
- August 24, 1998: Centocor receives approval for Remicade™ from the FDA
- October 5, 1998: Product available for wholesaler purchase
- Although a time span of 6 months has not clapsed since the approval of Remicade²⁰, Centoorr is requesting with this application, that Remicade²⁰ be granted a temporary J-code. Clinical data accumulated over the past 5 years was substantial enough for the FDA to grant Remicade²⁰ an expedited review, resulting in product approval. Remicade²⁰ is the first agent in its class (anti-TNF inhibitor) to be approved by the FDA. In addition, Remicade²⁰ is the only FDA approved therapy for the treatment of Crohn's Disease.
- 7. How are you currently marketing this product or service?

Centocor sells direct to wholesalers and specialty distributors. Remicadend is distributed nationally through these vendors.

8. Are Medicare carriers currently paying for this item?

Initial claims are just beginning to be filed. Discussions with Medicare carriers suggest that this product will be covered since Remicade^M is the only FDA approved therapy for Croim's disease.

What is the total Medicare, medicaid and private business annual volume in sales and or rental for the six months of marketing experience prior to submitting the request for coding consideration? (Do not estimate or provide projections – the information provided must represent actual volume of sales for the drug/product for the specific period of time indicated.)

Six months worth of data is not available. However, between October 5 and November 3, 1998 eighty-five (85) Modicare orders for Remicade^{ns} have been received.

10. Of the volume identified in #9, what is the percent of use in the following settings?



2

Health Care Finencing Administration Commun Procedure Coding System (HCPCS) Alpha-Numeric Coding Recommendation Forusat

Submitted by Centocar, Inc. November 4, 1998

- Physician office
- Ambulatory Care Clinic
- Patient Home
- Impatient Facility
- Other

(Based on discussions with clinicians, Remicade^{ns} will be predominantly delivered as an outpatient infusion, either in the physician office or other ambulatory site: infusion center, endoscopy suite, or hospital sutputient department.)

11. What is the wholesale cost of the item?

Remicade™ AWP: SS85.00 per 100mg vial

12. What is the retail cost of the item?

Remicade^{na} List Price: \$450.00 per 100mg vial

List any manufacturers or suppliers of similar items.

None

Identify the difference between this item and that of competitors.

There are no competitors for Remicade⁷⁰. Remicade⁷⁰ is the first agent in its class (anti-TNF inhibitor) to be approved, and the only agent approved by the FDA for use in Crohm's disease.

Recommendation submitted by:

Valeric Asbury, RN, BSN
Director, Corporate Accounts
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200 Great Valley Parkway
Malvera, PA 19355-1367
Phone: (610) 631-6351
Paxi: (610) 889-4769
Email: <u>nsheryv@ceotocor.com</u>

Valerie Asbury, Director, Corporate Accounts

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MDL-CEN00108054

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TAB N

Alternative Thresholds per Court Discussion, Trial Day 3, November 8, 2006



\$4,439,629 \$707,499 \$0 \$5,243,593

\$167,957,621 \$26,765,705 \$0 \$198,372,744

\$4,702,235 \$963,965 \$10,104 \$5,375,156

\$177,892,382 \$36,468,208 \$382,242 \$203,349,982

\$4,983,847 \$1,618,315 \$287,989 \$5,524,636

\$188,546,175 \$61,223,230 \$10,895,033 \$209,005,019

\$5,568,295 \$3,697,087 \$2,882,224 \$5,937,121

\$210,656,693 \$139,866,188 \$109,038,730 \$224,609,936

\$6,152,742 \$5,959,345 \$5,694,631 \$6,408,259

\$232,767,210 \$225,450,710 \$215,436,196 \$242,433,774

Astrazeneca Total Bristol-Myers Squibb Total Johnson & Johnson Total Schering-Plough Total

Liability Threshold = 30%

National Massachusetts

Liability Threshold = 25%
National Massachusetts

Liability Threshold = 20% National Massachusetts

Liability Threshold = 10%

National Massachusetts

Liability Threshold = 0%

National Massachusetts

WITH PREJUDGMENT INTEREST (2006\$)
Drugs by Defendant

Alternative Thresholds per Court Discussion, Trial Day 3, November 8, 2006: Class 2 Damages from 1991 to 2003

NOMINAL	Liability Threshold = 0%	eshold ≈ 0%	Llability Thre	Liability Threshold ≈ 10%	Liability Threshold = 20%	shold = 20%	Liability Thre	Liability Threshold = 25%	Liability Thre	Liability Threshold = 30%
Drugs by Defendant	National	Massachusetts	Nationa	Massachusetts	National	Massachusetts	National	Massachusetts	National	Massachusetts
Zoladex	\$153,211,134	\$4,049,834	\$139,875,712	\$3,697,339	\$126,540,289	\$3,344,843	\$120,038,886	\$3,172,991	\$113,811,751	\$3,008,389
AstraZeneca Totai	\$153,211,134	\$4,049,834	\$139,875,712	\$3,697,339	\$126,540,289	\$3,344,843	\$120,038,886	\$3,172,991	\$113,811,751	\$3,008,389
Blenoxane	\$	\$	9	\$	80	OS	G	Ş	Ş	é
Cytoxan	\$7,059,981	\$186,617	82	\$153,248	\$4,759,753	\$125,815	\$4,332,395	\$114,518	\$4,136,290	\$109.335
Etopophos	\$125,496	\$3,317		\$1,498	\$20,175	\$533	\$8,244	\$218	\$2,563	898
Paraplatin	\$44,365,279	\$1,172,709	23	\$720,043	\$10,117,641	\$267,440	\$3,712,558	\$98,134	\$455,402	\$12,038
Knbex	\$300,908	\$7,954		\$7,379	\$257,445	\$6,805	\$246,652	\$6,520	\$225,674	\$5,965
axol	\$54,357,691	\$1,436,838		\$827,567	\$9,391,681	\$248,251	\$3,929,958	\$103,881	\$2,388,762	\$63,142
vepesid	\$22,225,910	\$587,498	\$15,499,807	\$409,707	\$10,893,954	\$287,960	\$9,575,218	\$253,102	\$8,943,797	\$236,412
Bristol-Myers Squibb Total	\$128,435,264	\$3,394,933	\$80,181,616	\$2,119,443	\$35,440,649	\$936,804	\$21,805,025	\$576,373	\$16,152,489	\$426,959
Procrit Remicade	\$116,502,601 \$30,910,660	\$3,079,517 ³ \$817,062	\$56,513,508. \$17,880,855	\$1,493,823	\$2,177,938 \$4,851,051	\$57,570	\$139,556 \$86,895	\$3,689	0 8	6
Johnson & Johnson Total	\$147,413,262	\$3,896,579	\$74,394,364	\$1,966,468	\$7,028,989	\$185,797	\$226,451	\$5,986	0\$	\$
Albuterof	\$133,534,557	\$3,528	\$129,591,304	\$3,425,491	\$125,648,051	\$3,321,269	\$123,676,425	\$3,269,143	\$121.704.798	\$3.217.026
Intron	\$4,272,629	\$112,939	\$2,518,258	\$66,565	\$809,792	\$21,405	\$331,549	\$8,764	\$137,583	\$3,637
Proventi	\$6,909,052	\$182	\$4,226,679	\$111,724	\$2,318,851	\$61,294	\$1,792,961	\$47,393	\$1,322,513	\$34,958
emodar	\$2,066,737	\$54,630	\$944,046	\$24,954	\$100,250	\$2,650	\$23,547	\$622	\$12,623	\$334
Schering-Plough Total	\$146,782,975	\$3,879,919	\$137,280,287	\$3,628,734	\$128,876,944	\$3,406,608	\$125,824,481	\$3,325,922	\$123,177,517	\$3,255,955

Alternative Thresholds per Court Discussion, Trlal Day 3, November 8, 2006: Class 2 Damages from 1991 to 2004

NOMINAL	Liability Thr	Liability Threshold = 0%	I jahiliny The	Jahilihy Throshold = 10%	I John Wha	1000 - 1-1-4-				
				201 - 10/18	LIADURITY LITTLE	clability I nreshold = 20%	Liability Thre	Liability Threshold = 25%	Liability Thre	Liability Threshold = 30%
Drugs by Defendant	National	Massachusetts	National	Massachusetts	National	Massachusetts	National	Massachusetts	National	Massachusetts
Zoladex	\$180,882,758	\$4,781,279	\$165,704,642	\$4,380,076	\$150,526,526	\$3,978,872	\$143,103,777	\$3,782,666	\$135,955,295	\$3,593,710
AstraZeneca Total	\$180,882,758	\$4,781,279	\$165,704,642	\$4,380,076	\$150,526,526	\$3,978,872	\$143,103,777	\$3,782,666	\$135,955,295	\$3,593,710
Blenoxane	\$	0\$	80	80	Ů.	U\$	Ş	Ş	•	
Cytoxan	\$7,644,622	··	\$6,308,343	₩ •	\$5,231,164	\$138,276	\$4,784,792	\$126.477	\$4 569 733	\$120.702
Etopophos	\$127,720	_	\$56,671	\$1,498	\$20,175	\$533	\$8,244	\$218	\$2.563	36.42.1
Parapian	\$52,594,954	\$1,380,244	\$32,767,731	ĕ	\$12,942,844	\$342,119	\$5,186,644	\$137,099	\$610,852	\$16,147
Taxol	20,11.0¢		708,887		\$265,792	\$7,026	\$254,394	\$6,724	\$232,813	\$6,154
Vepesid	\$22,225,910	\$587,498	\$15,499,807	\$409,707	\$9,391,681	\$248,251 \$287,960	\$3,929,958	\$103,881	\$2,388,762	\$63,142
Bristol-Myers Squibb Total	\$137,262,718	\$3,628,269	\$86,229,415	\$2,279,305	\$38,745,611	\$1,024,164	\$23,739,249	\$627,500	\$16,748,520	\$442,714
Procrit Remicade	\$138,548,961 \$46,069,498	\$3,662,269 \$1,217,756	\$67,185,793 \$26,598,024	\$1,775,924 \$703,066	\$2,177,938 \$7,126,549	\$57,570 \$188,376	\$139,556 \$86,895	\$3,689 \$2,297	0\$	9,9,
Johnson & Johnson Total	\$184,618,460	\$4,880,025	\$93,783,816	\$2,478,990	\$9,304,487	\$245,946	\$226,451	\$5,986	0\$	- O.
Albuteroi	\$139,506,263	\$3,68;	\$135,527,905	\$3	\$131,549,547	\$3,477,253	\$129,560,368	\$3,424,673	\$127,571,189	\$3,372,093
Proventil	\$6,909,052	\$182,627	\$4,302,348	\$16,723	\$949,809	\$25,106	\$379,488	\$10,031	\$137,583	\$3,637
Temodar	\$2,944,499	\$7.1	\$1,416,531	\$37,443	\$207,717	\$5,491	\$48,984	\$1,295	\$7,322,513	\$34,858
Schering-Plough Total	\$154,214,957	\$4,076,368	\$144,073,664	\$3,808,303	\$135,025,925	\$3,569,144	\$131,781,801	\$3,483,392	\$129,056,632	\$3.411.355
WITH PREJUDGMENT INTEREST (2006\$)	Liability Threshold = 0%	eshold = 0%	Liability Threshold = 10%	shold = 10%	Liability Threshold = 20%	shold = 20%	Llability Threshold a 25%	shold = 25%	Liability Threshold = 30%	shold = 30%
Drugs by Defendant	National	Massachusetts	National	Massachusetts	National	Massachusetts	National	Massachusetts	National	Massachusatte
			<u> </u>							Wildering and a second

INTEREST (2006\$)	ability Thre	jability Threshold = 0%	i lability Throshold = 10%	shold = 10%	1 lobility Thus	/a00 = 1704,0	# - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -			
			2	0/01 - 0010		dollary threshold = 20%	LIADIIITY I nre	lability Inreshold = 25%	Liability Threshold = 30%	ehold = 30%
Drugs by Defendant	National	National Massachusetts	National	(ational Massachusetts	National	National Massachusetts	National	National Massachusetts	National	National Massachusetts
-	264,456,743	\$6,990,393	\$240 235 974	SR 350 165	\$218 015 205	•	000 000			
Deletal Misons Carellah Total	0000000			00000	007,010,013	7	9204,300,200	45,400,434	\$193,316,399	\$5,109,938
	004,500,00		\$146,792,134	\$3,880,161	\$65,008,070	σ,	\$38,683,282	\$1 022 515	080 AAA 703	C70E E44
Johnson & Johnson Total \$25	\$258,043,574	\$6,820,873	\$131.243.524	\$3.469.164	\$13 500 933	\$356 B74	4300 040	940.40	007/011/17	10,0219
-	020 010 030		400 000		00000	יסיססי	\$305,242	401,014	24	20\$
7	0/0/11/0/0	40,033,233	\$232,389,708	\$6,142,764	\$216,046,829	\$5,710,772	\$210.172.302	\$5.555.491	\$205 105 390	\$\$ 404 KE7

Alternative Thresholds per Court Discussion, Trial Day 3, November 8, 2006: Class 3 Damages from 1991 to 2003

NOMINAL	Liability Threshold = 25%	shold = 25%	Liability Thre	Liability Threshold = 30%
Drugs by Defendant	National	Massachusetta	National	Massachusetts
Zoladex	\$237,932,098	\$6,289,266	\$226,683,514	\$5,991,932
AstraZeneca Total	\$237,932,098	\$6,289,266	\$226,683,514	\$5,991,932
Blenoxane	\$4,785,782	\$126,503	\$93,493	\$2,471
Cytoxan	\$118 410	53 130	\$22	9
Paraplatin	\$89,328,075	\$2,361,212	\$31,980,664	\$845.346
Rubex	\$0	0\$	08	09
Taxol	\$71,049,499	\$1,878,053	\$6,942,080	\$183,500
Vepesid	\$5,444,675	\$143,919	\$2,716,549	\$71,807
Bristol-Myers Squibb Total	\$170,726,441	\$4,512,817	\$41,751,363	\$1,103,615
Procrit Remicade	\$16,512,634 \$120,742,388	\$438,479	\$8,958,183	\$236,791
Johnson & Johnson Total	\$137,255,022	\$3,628,066	\$8,958,163	\$236,791
Albuterol	80	O\$	8	0\$
Intron	\$14,423,931	\$381,268	\$5,528,801	\$146,143
Proventil	\$2,183,124	\$57,707	\$1,337,408	\$35,352
	•	3	3	9
Schering-Plough Total	\$16,607,055	\$438,975	\$6,866,209	\$181,495

WITH PREJUDGMENT INTEREST (2006\$)	Liability Thre	Liability Threshold = 25%	Liability Thre	iability Threshold = 30%
Drugs by Defendant	National	National Massachusetts	National	National Massachusetts
AstraZeneca Total Bristol-Myers Squlbb Total Johnson & Johnson Total Schering-Plough Total	\$302,123,405 \$226,423,789 \$163,317,057 \$24,398,487	\$7,986,037 \$5,985,067 \$4,316,965 \$644,926	\$287,176,936 \$50,640,054 \$11,155,281 \$10,648,583	\$7,590,956 \$1,338,570 \$294,868 \$281,474

INTEREST (2006\$)	Liability Thre	Liability Threshold = 25%	Liability Thre	iability Threshold = 30%
ugs by Defendant	National	National Massachusetts	National	National Massachuset
total Total	307 604 6064		000 011	
suatellara lotal	\$30K, K3,403		956,371,7854	CB() CB() / SP
istol-Myers Squibb Total	\$226,423,789	\$5,985,067	\$50,640,054	\$1,338,57
hnson & Johnson Total	\$163,317,057	\$4,316,965	\$11,155,281	\$294,86
chering-Plough Total	\$24,398,487	\$644,926	\$10,648,583	\$281,47

Alternative Thresholds per Court Discussion, Trial Day 3, November 8, 2006: Class 3 Damages from 1991 to October 2006

NOMINAL	Liability Threshold = 25%	shold = 25%	Liability Thre	Liability Threshold = 30%
Drugs by Defendant	National	Massachusetts	National	Massachusetts
Zoladex	\$375,630,746	\$9,929,059	\$359,455,174	\$9,501,489
AstraZeneca Total	\$375,630,748	\$9,929,059	\$359,455,174	\$9,501,489
Blenoxane	\$4,785,782	\$126,503	\$93,493	\$2,471
Etopophos	\$118,410	\$3,130	\$18,577	\$491
Paraplatin	\$115,155,017	\$3,043,896	\$47,199,646	\$1,247,630
Kubex	\$71 049 499	\$1 878 053	\$000 080	\$0\$
Vepesid	\$5,444,675	\$143,919	\$2,716,549	\$71,807
Bristol-Myers Squibb Total	\$196,553,383	\$5,195,501	\$56,970,345	\$1,505,899
Procrit Remicade	\$32,604,732 \$247,089,038	\$861,842	\$0 \$8,958,163	\$236,791
Johnson & Johnson Total	\$279,693,770	\$7,393,154	\$8,958,163	\$236,791
Albuteroi Intron Proventil Temodar	\$21,469,804 \$2,183,124	\$0 \$567,512 \$57,707	\$0 \$8,953,949 \$1,337,408 \$0	\$236,680 \$35,352 \$0
Schering-Plough Total	\$23,652,928	\$625,219	\$10,291,358	\$272,032

WITH PREJUDGMENT INTEREST (2006\$)	Liability Thre	Liability Threshold = 25%	Llability Thre	lability Threshold = 30%
Drugs by Defendant	National	National Massachusetts	National	National Massachuset
AstraZeneca Total	\$445 922 342	\$11.787.078	\$425 829 199	\$11.255.04
Bristol-Myers Squibb Total	\$254,504,160	\$6,727,316	\$67,186,909	\$1,775,96
Johnson & Johnson Total	\$312,289,442	\$8,254,756	\$11,155,281	\$294,86
Schering-Plough Total	\$31,774,022	\$839,884	\$14,249,904	\$376,66

INTEREST (2006\$)	Liability Thre	Liability Threshold = 25%	Llability Thre	lability Threshold ≈ 30%
Drugs by Defendant	National	National Massachusetts	National	National Massachusetts
AstraZeneca Total	\$445,922,342	\$11.787.078	\$425.829.199	\$11,255,958
Bristol-Myers Squibb Total	\$254,504,160	\$6,727,316	\$67,186,909	\$1,775,964
Johnson & Johnson Total	\$312,289,442		\$11,155,281	\$294,868
Schering-Plough Total	\$31,774,022	\$839,884	\$14,249,904	\$376,668

TAB O



UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY)

AVERAGE WHOLESALE PRICE) MDL NO. 1456

LITIGATION) Civil Action No. 01-12257-PBS

Hon. Patti B. Saris

THIS DOCUMENT RELATES TO)

TRIAL OF CLASS 2 AND)

CLASS 3 CLAIMS)

TRIAL DECLARATION OF JAYSON S. DUKES

I. QUALIFICATIONS AND COMPENSATION

- 1. I am a Managing Director in the Forensic and Litigation Consulting Practice of FTI Consulting ("FTI"). FTI is a multi-disciplinary consulting firm with practices in financial restructuring, forensic and litigation consulting, and economic consulting.
- 2. I am a Certified Public Accountant and I received a Bachelor's Degree in Accounting from the University of Georgia.
- 3. I have assisted in resolving disputes across a wide variety of industries for nearly 15 years. I have advised healthcare providers, pharmaceutical companies, and other life sciences clients on financial, accounting, and economic matters. My current clients include Bristol-Myers Squibb, Wyeth, Johnson & Johnson, and HCA.
- 4. I have particular expertise in the analysis of pharmaceutical pricing practices, including rebating, discounting, and other commonly used financial incentives. My curriculum vitae is annexed to this Declaration as DX 2784A.
- 5. While I have directed all of the work connected with this engagement, I have been assisted by several other FTI employees.
- 6. FTI's fees for this engagement are based upon time expended and expenses incurred. My billing rate is \$424 per hour. The rates charged by the other FTI employees who have assisted me in this engagement range from \$195 per hour to \$495 per hour.

II. SCOPE OF ASSIGNMENT

7. FTI was retained by Patterson, Belknap, Webb & Tyler LLP, attorneys for the Johnson & Johnson Defendants, to perform data analyses and financial calculations relating to Procrit®, a product sold by Ortho Biotech Products, L.P., and Remicade, a product sold by Centocor, Inc.

A. Initial Assignment

- 8. FTI was asked to calculate the average selling price ("ASP") for Procrit and Remicade, based on units sold at each price point, by product National Drug Code ("NDC"), by year. We were asked to calculate ASPs excluding the same classes of trade purportedly excluded by plaintiffs' expert, Dr. Raymond S. Hartman, as described in his reports dated December 15, 2005 and February 3, 2006.
- 9. Based on these ASP calculations, FTI was asked to calculate the "spreads" between

¹ The methodologies used by Dr. Hartman and FTI to calculate ASPs for purposes of this litigation differ from the methodology that CMS requires manufacturers to use to calculate the ASPs that they submit pursuant to the Medicare Modernization Act.

the above-described ASPs and the published AWPs for Procrit and Remicade, again using Dr. Hartman's methodologies for calculating the "spread".

B. Subsequent Assignment

10. Dr. Hartman submitted his Direct Testimony in this case on November 1, 2006. Dr. Hartman's Direct Testimony includes revised ASP and "spread" calculations that differ from those within his reports dated December 15, 2005 and February 3, 2006. FTI was asked to examine and comment on Dr. Hartman's revised calculations.

III. SUMMARY OF PRIOR REPORTS AND OPINIONS

- 11. Dr. Hartman's theory of liability is based on the size of the "spread" between a drug's ASP and its AWP. In order to determine liability, Dr. Hartman proposed a definition of ASP, and then attempted to calculate ASPs in accordance with his definition. He then determined the difference between the ASP and the AWP, to determine the size of the "spread." Finally, he expressed the "spread" as a percentage, calculated as the difference between the ASP and the AWP, divided by the ASP.
- 12. In order for Dr. Hartman's "spread" calculations to be reflect a true average, he must correctly calculate the drug's ASP, and he must determine the difference between that ASP and the correct AWP. If either the ASP or the AWP is incorrect, the resulting "spread" will also be incorrect.
- 13. My review of the ASP and "spread" calculations in Dr. Hartman's December 15, 2005 and February 3, 2006 reports uncovered numerous calculation errors resulting from Dr. Hartman's failure to correctly apply his intended methodology. That methodology required him to comprehensively identify and remove from his calculations all sales transactions pertaining to units of Procrit and Remicade distributed to hospitals, managed care entities, and the government. As a result of these and other errors, many of Dr. Hartman's original calculations understated the ASPs for Procrit and Remicade, and therefore overstated the size of their "spreads."
- 14. Specifically, in his December 15, 2005 report, Dr. Hartman examined 116 Procrit NDCs during the period 1991 to 2003, and concluded that the "spread" on 16 Procrit NDCs exceeded 30% in particular years. He also concluded that the "spread" on Remicade exceeded 30% in each year from 1998 to 2003.
- 15. I submitted a responsive report in which I pointed out numerous errors in Dr. Hartman's December 15, 2005 calculations and observations, which resulted in inaccurate reporting of "spreads" for Procrit and Remicade.²

² See Number 30 and Number 32 within Declaration of Jayson S. Dukes in Support of the Johnson & Johnson Defendants' Motion for Summary Judgment as to Class 1 and Class 2 (Corrected) (May 8, 2006), detailing errors in Dr. Hartman's ASP and "spread" calculations.

IV. COMMENTS ON DR. HARTMAN'S DIRECT TESTIMONY

16. As part of his Direct Testimony dated November 1, 2006, Dr. Hartman revised his ASP and "spread" calculations for Procrit and Remicade. These revised calculations differ from the calculations in his reports dated December 15, 2005 and February 3, 2006.

A. Dr. Hartman's Revised Procrit Calculations

- 17. Based on his revised ASP and "spread" calculations for Procrit, Dr. Hartman has now concluded that <u>none</u> of the "spreads" on any of Procrit's NDCs ever exceeded 30%. While I have not reviewed Dr. Hartman's revised Procrit calculations in detail, they appear generally consistent with my calculations.
- 18. Based on his revised ASP and "spread" calculations, Dr. Hartman finds no liability or damages for Procrit for Class 3.5
- 19. Dr. Hartman finds liability and damages for Procrit for Class 2 based on a legal theory that Medicare and Massachusetts law required a "spread" of "zero." Inasmuch as this is a legal theory, I am unable to comment further.

B. Dr. Hartman's Revised Remicade Calculations

20. I was advised by Centocor that during the period at issue in this case, Centocor did not extend discounts or rebates to physicians for purchases of Remicade. Nevertheless, in his December 15, 2005 report, Dr. Hartman calculated the following ASPs and "spreads" on Remicade:

	Remica	de "ASPs" Per H	artman Dec. 200	5 Report	
1998	1999	2000	2001	2002	2003
\$447.26	\$458.23	\$486.17	\$508.25	\$516.65	\$514.98

	Remicado	"Spreads" Per	Hartman Dec. 20	05 Report	
1998	1999	2000	2001	2002	2003
30.8%	33.4%	31.9%	36.1%	33.9%	34.3%

³ <u>See</u> Direct Testimony of Raymond S. Hartman (Nov. 1, 2006) ("Hartman Direct") at Attachment G.3.a ("Johnson & Johnson Annual Average Sales Price") and Attachment G.3.c ("Johnson & Johnson Annual Spreads").

⁴ See Hartman Direct at Attachment G.3.c (Johnson & Johnson Annual Spreads").

⁵ <u>See</u> Hartman Direct at Attachment I.3 ("Johnson & Johnson Drugs Subject to Liability") and Attachment J.3.a ("Summary of Johnson & Johnson Massachusetts Damages by Class and By Drug").

21. In his November 1, 2006 Direct Testimony, Dr. Hartman revised his ASP and "spread" calculations for Remicade as follows⁶:

	Revised Remid	cade "ASPs" Per	Hartman Nov. 2	006 Testimony	
1998	1999	2000	2001	2002	2003
\$450.68	\$462.77	\$499.15	\$524.32	\$532.24	\$532.18

	Revised Remica	de "Spreads" Pe	r Hartman Nov.	2006 Testimony	
1998	1999	2000	2001	2002	2003
29.8%	32.1%	28.5%	31.9%	29.9%	30.0%

C. Dr. Hartman's Revised "Spread" Calculations Used the Wrong AWPs

- 22. As discussed below, Dr. Hartman's revised calculations of Remicade's "spreads" in 1999 and 2001 are incorrect because he used the wrong AWPs. Correcting for this error, I conclude that the Remicade "spreads" in 1999 and 2001 were less than 30%.
- 23. As noted above, in order to accurately calculate the "spread" in a given year, Dr. Hartman must accurately calculate the ASP and must also select the appropriate AWP, since the "spread" is simply the difference between the ASP and the AWP. In calculating the "spreads" for Remicade, Dr. Hartman used the following AWPs⁷:

	Remicade	"AWPs" Per Ha	rtman Nov. 2006	Testimony	
1998	1999	2000	2001	2002	2003
\$585.00	\$611.33	\$641.28	\$691.61	\$691.61	\$691.61

- 24. Selecting the right AWP to use in the "spread" calculation is seemingly non-controversial given that AWPs are published. Indeed, in a year where the AWP does not change, there would only be one AWP to choose from. That was the case in three out of four years in which Dr. Hartman concludes that Remicade's "spread" was at/less than 30% (i.e., in 1998, 2002, and 2003).
- 25. However, that was not the case in either of the two years in which Dr. Hartman concludes that Remicade's "spread" was greater than 30% (i.e., in 1999 and 2001). In those years, Remicade's list price and AWP changed during the year, because Centocor increased the list price. Consequently, in each of those years, Dr. Hartman had to select which AWP, if either, to use in calculating Remicade's "spread."

⁶ <u>See Hartman Direct at Attachment G.3.a</u> ("Johnson & Johnson Annual Average Sales Price") and Attachment G.3.c ("Johnson & Johnson Annual Spreads").

⁷ See Hartman Direct at Attachment G.3.b ("Johnson & Johnson Annual AWPs").

- 26. In 1999, Remicade's AWP was \$585.00 for part of the year (from January 1, 1999 through June 17, 1999), and \$611.33 during the rest of the year (from June 18, 1999 through December 31, 1999). In 2001, Remicade's AWP was \$665.65 for part of the year (from January 1, 2001 through June 13, 2001), and \$691.61 during the rest of the year (from June 14, 2001 through December 31, 2001). In performing his "spread" calculations, Dr. Hartman chose to use the AWPs in effect on June 30th during those years, (i.e., \$611.33 in 1999, and \$691.61 in 2001).
- 27. Dr. Hartman's finding that Remicade's spread was 32.1% 1999 and 31.9% in 2001 is driven by his decision to compare his ASP figures to the AWPs in effect on June 30th, which were the higher of the two AWPs in effect during each of those years, as follows:⁹

	1999	2001
Higher AWP	\$611.33	\$691.61
ASP	\$462.77	\$524.32
Difference (% Spread)	\$148.56 (32.1%)	\$167.29 (31.9%)

28. Alternatively, instead of choosing the AWPs in effect on June 30th 1999 and 2001, Dr. Hartman should have based his calculations on a "weighted average" of the AWPs. Since Dr. Hartman's ASPs are based on units sold at each price point and he is in effect calculating a weighted average selling price, it is logical and appropriate that a weighted average ASP should be compared to a weighted average AWP. The effect on the "spreads" of using a weighted average AWP is illustrated in the following table:

	1999	2001
Weighted Average AWP	\$598.47	\$679.89
ASP	\$462.77	\$524.32
Difference (% Spread)	\$135.70 (29.3%)	\$155.57 (29.7%)

 A table showing all Procrit and Remicade "spreads" from 1991 through 2003, based on a comparison of Dr. Hartman's November 1, 2006 ASPs with the weighted average AWPs FTI calculated, is attached as DX 2873.

⁸ According to Plaintiffs' counsel, Dr. Hartman picked whichever AWP was in effect as of June 30th. See Letter from Thomas M. Sobel to Andrew D. Schau (Nov. 7, 2006).

⁹ Had he elected to compare his ASPs to the lower of the AWPs in effect during those years, he would have concluded that Remicade's spread was 26.4% in 1999 and 27.0% 2001.

D. Remicade "Damages" Analysis

- 30. Based on his conclusion that the Remicade "spread" was 32.1% in 1999 and 31.9% in 2001, Dr. Hartman finds damages for Class 3 of \$27,868 in 1999 and \$208,923 in 2001¹⁰. Dr. Hartman does not find damages for Class 3 in 1998, 2000, 2002, and 2003.
- 31. Based on my conclusion that Remicade's "spreads" in 1999 and 2001 were less than 30%, I conclude, contrary to Dr. Hartman, that there is no liability or damages for Class 3 in 1999 and 2001, even assuming that Dr. Hartman's liability and damages theories are accepted.
- 32. Dr. Hartman finds liability and damages for Remicade for Class 2 in all years based on a legal theory that Medicare and Massachusetts law required a "zero" spread. Inasmuch as this is a legal theory, I am unable to comment further.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 11 16, 2006

Jayson S. Dukes

 $^{^{10}}$ See Hartman Direct at Attachment J.3.a ("Summary of Johnson & Johnson Massachusetts Damages by Class and by Drug").

Attachment 1

Curriculum Vitae

Name:

Jayson S. Dukes

Addresses:

Business:

FTI Consulting, Inc.

One Atlantic Center

1201 West Peachtree Street

Suite 500

Atlanta, Georgia 30309

Telephone:

(404) 460-6221

(404) 873-3735

Home: 755 East Morningside Drive

Atlanta, Georgia 30324

Birth:

September 7, 1969

Laramie, Wyoming

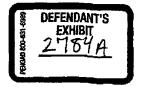
Education:

B.B.A. University Georgia, June 1991

Major in Accounting

Professional Certifications:

Certified Public Accountant – 1996



Attachment 1

Relevant Work Experience

FTI Consulting, Inc. Managing Director Director

2005 - Present 2003 - 2004

Manage engagements occurring in the Atlanta Office of FTI's Dispute Advisory Services Practice. This Practice regularly conducts Dispute Advisory Services and Investigative Advisory Services.

KPMG, LLP Director

2002 - 2003

Managed engagements occurring in the Atlanta Office of KPMG's Forensics Practice. This Practice regularly conducts Dispute Advisory Services and Investigative Advisory Services.

Arthur Andersen

 Director
 1999 - 2002

 Manager
 1995 - 1999

 Sr. Consultant
 1993 - 1995

Managed engagements occurring in the Atlanta and Los Angeles Offices of Arthur Andersen's Value Solutions Practice. This Practice regularly conducted Legal Consulting Services, Corporate Recovery Services and Bankruptcy Consulting Services.

Arthur Andersen Staff Accountant

1991 - 1993

Performed audit, and management consulting services for clients including banks, manufacturers, and not-for-profit organizations.



Annual Spread Calculations based on Hartman's Direct Testimony Dated November 1,2006 and FTI's Weighted Average AWPs

NDC	Product	Product Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
00062740003	Procrit	PROCRIT 40001/ML AMG	22 6%	23.7%	21 8%										
50104759000	Dragarit	н	79 66												
	11001	FRUCKI I TOUGOU/MIL AIMG	77.77	63.0%	%2.77										
00062740201	Procrit	PROCRIT 2000U/ML AMG	24.4%	24.8%	22.3%										
00062740501	Procrit	PROCRIT 3000U/ML AMG	21.0%	25.2%	21 4%										
59676030201	Procrit	PROCRIT 2000 U/MI, 6'S				22.4%	21.6%	21.9%	21.5%	21.4%	22.8%	20.5%	22.2%	19.8%	17.6%
59676030202	Procrit	PROCRUT 2000 U/ML, INSTITUTIO			20.5%	21.4%	22.0%	25.2%		24.7%	22.7%	19.4%	25.3%	27.6%	21.8%
59676030301	Procrit	PROCRIT 3000 U/ML 6'S				22.7%	22.1%	22.1%	21.7%	21.5%	22.5%	21.2%	22.7%	20.5%	18.6%
59676030302	Procrit	PROCRIT 3000 U/ML 25'S			21.5%	22.5%	23.4%	24.4%		23.6%	22.1%	19.7%	24.1%	24.6%	20.8%
59676030401	Procrit	PROCRIT 4000 U/ML 6'S				22.7%	21.6%	21.7%	21.2%	21.0%	22.2%	21.3%	22.7%	20.9%	%1.61
59676030402	Procrit	PROCRIT 4000 U/MI. 25'S			23.8%	23.4%	24.2%	25.3%		23.0%	22.6%	19.8%	24.1%	21.1%	21.1%
59676031001	Procrit	PROCRIT 10000 U/ML 6'S			22.8%	22.5%	21.8%	22.1%	22.2%	21.5%	23.2%	22.0%	23.3%	21.4%	20.7%
59676031002	Procrit	PROCRIT 10000 U/ML 25'S			24.4%	22.4%	22.3%	24.2%		25.6%	25.5%	23.0%	26.8%	23.5%	24.4%
59676031201	Procrit	PROCRIT 10,000 U/ML, MULTIDOS					20.5%	23.4%	26.4%	24.9%	25.0%	22.7%	25.8%	23.7%	24.3%
	Procrit	PROCRIT 20,000 U/ML - 1ML							23.4%	25.0%	25.6%	25.7%	27.3%	25.6%	26.0%
59676034001	Procrit	PROCRIT 40000 U/ML 4'S						•			24.4%	25.3%	27.2%	25.5%	26.0%
57894003001	Remicad	Remicade C1683 REMICADE 1PCK US PD								29.8%	29.3%	28.5%	29.7%	29.9%	30.0%



Contains Confidential Information Subject to Protective Order

TAB P

1	IN THE UNITED S	STATES DISTRICT COURT
	FOR THE DISTR	CT OF MASSACHUSETTS
2		
3		
	In Re:)
4	PHARMACEUTICAL INDUSTRY) CA No. 01-12257-PBS
	AVERAGE WHOLESALE PRICE) MDL No. 1456
5	LITIGATION) Pages 17-1 - 17-132
6		
7		
	BENCH TRIA	AL - DAY SEVENTEEN
8		
	BEFORE THE HON	ORABLE PATTI B. SARIS
9	UNITED STA	ATES DISTRICT JUDGE
10		
11		
12		
13		
		United States District Court
14		1 Courthouse Way, Courtroom 19
		Boston, Massachusetts
15		December 11, 2006, 9:15 a.m.
16		
17		
18		
19		
20		
21		
22		
	TIMOTHY J.	WILLETTE, RDR, CRR
23		COURT REPORTER
		ates District Court
24		use Way, Room 3205
		on, MA 02210
25		.7) 345-6787

4

1.					
2					
3					
4					
		I N D E	X		
5					
6	WITNESS	DIRECT	CROSS	REDIRECT	RECROSS
7					
	Raymond Hartman (Resumed)		17-6	17-51	17-76
8					17-94
9	Jayson Dukes	17-99	17-109	17-129	
10					
11					
12					
	EXHIBITS	PAG	E		
13					
	2961	17-	43		
14	4007	17-	52		
	4012	17-	58		
15					
	4028, 4029, 4030,				
16	4032, 4033, 4034	17-	65		
17	4008	17-	68		
	4009	17-	70		
18	4010	17-	72		
	4011	17-	75		
19					
	2658, 2655, 2656	17-	91		
20					
	2784-A, 2873	17-	109		
21					
22					
23					
24					
25					

- 1 THE COURT: And where does that put you.
- THE WITNESS: It puts you around -- let me see.
- 3 Q. Is it still below 30 percent?
- 4 A. Yes.
- 5 THE COURT: That's all that matters.
- Q. And in his direct testimony, Dr. Hartman was asked some
- questions about the year 2000 when there were two price
- 8 increases in effect that year. Did you look at the effect of
- 9 the price increases in 2000 on the calculation of the spread?
- 10 A. Yes.
- 11 Q. Okay. And if you can take a look at slide 9, please.
- 12 Did you find that in 2000, there was any effect on the
- 13 calculation of the spread?
- 14 A. Not as it is rounded to one decimal point, no.
- 15 Q. Lastly, can you take a look at slide 10, please? And
- 16 can you explain to the Court what's shown on slide 10?
- 17 A. Slide 10 are -- the first line are Hartman's spread
- 18 calculation based on his November 1 declaration.
- 19 Q. That's for Remicade?
- 20 A. That's for Remicade, yes.
- Q. And what's on line 2?
- 22 A. The line 2 is taking Hartman's ASP calculations per his
- November 1 declaration and comparing those to a weighted
- 24 average AWP in order to calculate the spread.
- Q. And is it fair to say when you compare Dr. Hartman's

- ASPs to a weighted average AWP, all of the spreads for
- 2 Remicade are equal to or less than 30 percent?
- 3 A. Yes.
- 4 THE COURT: Is that still true if you just average?
- 5 THE WITNESS: I believe so, yes.
- 6 MR. SCHAU: Your Honor, I offer Defendants' Exhibit
- 7 2784-A, which is his curriculum vitae attached to his direct
- 8 testimony, and 2873, which is a calculation of weighted
- 9 average spreads for all Procrit and Remicade NDCs.
- 10 THE COURT: Okay, fine. Thank you.
- 11 Any cross? We can finish this by 1.
- MR. SOBOL: Gee, thanks.
- 13 THE COURT: I mean, this is really just identical
- 14 to what his direct was, so --
- MR. SOBOL: Right.
- 16 CROSS-EXAMINATION
- 17 BY MR. SOBOL:
- 18 Q. Good afternoon. Before you prepared your report in this
- 19 case, you had been working on the AWP case, correct?
- 20 A. Yes.
- Q. And by the time that you had sat down to prepare your
- 22 report for the direct testimony, before you had done that,
- 23 your firm had billed the lawyers in this case more than
- 24 \$2.5 million for the work you had already done even before
- you did this report, correct?